# **OCUFLOX®**

### **Consumer Medicine Information (CMI) summary**

The <u>full CMI</u> on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

# 1. Why am I using OCUFLOX®?

OCUFLOX® eye drops contain the active ingredient ofloxacin. OCUFLOX® is used in adults to treat ulcers on the front layer of the eye (the cornea) and severe eye infection (conjunctivitis).

For more information, see Section <u>1. Why am I using</u> OCUFLOX®? in the full CMI.

# 2. What should I know before I use OCUFLOX®?

Check the list of ingredients at the end of the CMI. Do not use OCUFLOX® if you have ever had an allergic reaction to any of them.

Talk to your doctor before you use this medicine if he/she is not aware that you have any other medical conditions, take any other medicines, or

# are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I use OCUFLOX®? in the full CMI.

# 3. What if I am taking other medicines?

Some medicines may interfere with OCUFLOX® and affect how it works, or OCUFLOX® may interfere with other medicines and affect how they work. For more information see Section 3. What if I am taking other medicines? in the full CMI.

# 4. How do I use OCUFLOX®?

- Your doctor will advise how many drops to use depending on your condition
- Your doctor will advise when to start using the drops and when to finish.
- Do not stop using OCUFLOX® earlier than instructed without checking with your doctor, even if you feel better.

More instructions can be found in Section 4. How do I use OCUFLOX®? in the full CMI.

# 5. What should I know while using OCUFLOX®?

Follow all your doctor's instructions carefully.

	<ul> <li>Tell your doctor if your infection appears to be getting worse, or you experience an injury, or have surgery in your eye(s).</li> <li>Remind any doctor, dentist, pharmacist, or optometrist you visit that you are using OCUFLOX®.</li> </ul>
Things you should not do	<ul> <li>Do not stop using OCUFLOX® earlier than instructed or use it for longer than instructed without checking with your doctor</li> <li>Avoid direct exposure to sunlight or artificial ultraviolet light when using OCUFLOX®.</li> <li>Do not touch the dropper tip against your eye, eyelid or any surface.</li> <li>Do not use OCUFLOX® while you are wearing</li> </ul>
Driving or using machines	<ul><li>soft contact lenses.</li><li>Wait for your vision to clear after using</li></ul>

	OCUFLOX® before you drive or use machines.
Drinking alcohol	<ul> <li>There is no information on the effects of taking OCUFLOX® with alcohol.</li> </ul>
Looking after your medicine	<ul> <li>Follow all instructions on the carton and bottle label.</li> <li>Store it in a cool place, below 25°C, away from heat, or sunlight.</li> </ul>

For more information, see Section <u>5. What should I know while using OCUFLOX®?</u> in the full CMI.

# 6. Are there any side effects?

Burning, stinging, watering eye, itchy eye, eyelid, feeling something in the eye, unable to tolerate sunlight, eye redness, inflamed eye, swelling of eyelid, face, dry eye, eye pain, skin rash, blurred vision, feeling dizzy, severe allergic reaction.

For more information, including what to do if you have any side effects, see Section <u>6. Are there any side</u> <u>effects?</u> in the full CMI.

# **OCUFLOX®** (ock-you-flox)

**Active ingredient:** *ofloxacin* (oh-flox-ah-sin)

### **Consumer Medicine Information (CMI)**

This leaflet provides important information about using OCUFLOX® eye drops. You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using OCUFLOX®.

#### Where to find information in this leaflet:

- 1. Why am I using OCUFLOX®?
- 2. What should I know before I use OCUFLOX®?
- 3. What if I am taking other medicines?
- 4. How do I use OCUFLOX®?
- 5. What should I know while using OCUFLOX®?
- 6. Are there any side effects?
- 7. Product details

# 1. Why am I using OCUFLOX®?

OCUFLOX® contains the active ingredient ofloxacin. Ofloxacin is an antibiotic and acts by killing a wide range of bacteria that cause certain eye infections.

OCUFLOX® is used in adults to treat ulcers on the front layer of the eye (corneal ulcers) and severe eye infections (conjunctivitis).

# 2. What should I know before I use OCUFLOX®?

# **Warnings**

#### Do not use OCUFLOX® if:

- you are allergic to ofloxacin, or any of the ingredients listed at the end of this leaflet.
- you are allergic to any similar antibiotics, such as ciprofloxacin, moxifloxacin, nalidixic acid.
- the seal around the cap is broken.
- the bottle/packaging shows signs of tampering.
- the product does not look quite right.
- the expiry date on the bottle has passed.

## Check with your doctor if you:

- have or have had unusual sensitivity to sunlight or artificial ultraviolet light
- take any medicines for any other condition.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

# **Pregnancy and breastfeeding**

Make sure your doctor is aware that you are pregnant or plan to become pregnant or are breastfeeding or intend to breastfeed.

OCUFLOX® is not recommended in pregnant or breastfeeding women.

#### Children

OCUFLOX® should not be used in children younger than 12 years of age.

# 3. What if I am taking other medicines?

It is not expected that OCUFLOX will interact with other medicines, however tell your optical practitioner, doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins, or supplements that you buy without a prescription from your pharmacy, supermarket, or health food store.

Check with your optical practitioner, doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect OCUFLOX®.

# 4. How do I use OCUFLOX®?

## How much to use, and when to use OCUFLOX®

Your doctor will tell you how many drops you need to use each day. Use OCUFLOX® as prescribed by your doctor.

Do not stop using OCUFLOX® earlier than instructed without checking with your doctor, even if you feel better.

#### **Corneal ulcer:**

- 1 to 2 drops in the affected eye(s) every 30 minutes (during waking hours) and also 1 to 2 drops into the affected eye(s) during the night 4 hours after retiring and 2 hours after this, for 2 days, then
- 1 to 2 drops into the affected eye(s) every hour (during waking hours) for 5 days, then
- 1 to 2 drops into the affected eye(s) 4 times each day until your doctor tells you to stop.

### **Conjunctivitis:**

- 1 drop in the affected eye(s) every 4 hours for the first 2 days, then
- 1 drop every 6 hours for up to 8 days
- You should not use these drops for longer than 10 days without checking with your doctor.

#### How to use OCUFLOX®

- 1. These eye drops are for topical use only.
- 2. Wash your hands well with soap and water.

- 3. If you wear soft contact lenses, remove them before using OCUFLOX®.
- 4. Tear off the protective seal on any new bottle and throw the seal away. Remove the lid/cap.
- 5. Hold the bottle upside down in one hand between your thumb and index finger.
- 6. Using your other hand, gently pull down your lower eyelid to form a pouch or pocket.
- 7. Tilt your head back and look up. This might be easier if you are sitting or lying down.
- 8. Put the tip of the bottle close to your lower eyelid.

  Do not let the tip touch your eye, eyelid or any other surface.
- 9. Release one drop into the pouch or pocket formed between your eye and eyelid by gently squeezing the bottle.
- 10If a drop misses your eye, try again, and wipe off any excess that runs down your cheek.
- 11Close your eye. Do not blink or rub your eye.
- 12While your eye is closed, place your index finger against the inside corner of your eye and press against your nose for about two minutes. This will help to stop the medicine from draining through the tear duct to the nose and throat, from where it can be absorbed into other parts of your body.
- 13Replace the lid/cap, sealing it tightly.
- 14Wash your hands again with soap and water.
- 15If you wear soft contact lenses, wait 15 minutes before replacing your contact lenses.

## If you forget to use OCUFLOX®

It is important that you use OCUFLOX® strictly as instructed.

If you forget to use OCUFLOX® and it is almost time for your next dose, skip the missed dose and use the drops when you are next meant to.

Otherwise, use the drops as soon as you remember, and then go back to using them as you would normally. If you are not sure whether to skip the dose, talk to your doctor or pharmacist.

Do not use a double dose to make up for the dose you missed.

## If you use too much OCUFLOX®

Immediately rinse your eyes with warm water.

# If OCUFLOX® is accidentally swallowed, immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there appear to be no signs of discomfort or poisoning.

# 5. What should I know while using OCUFLOX®?

# Things you should do

- If you wear soft contact lenses, remove them before using OCUFLOX®, and wait at least 15 minutes before inserting them again. The preservative in OCUFLOX® eye drops (benzalkonium chloride) may be absorbed and cause discolouration of soft contact lenses.
- Avoid direct exposure to sunlight or artificial ultraviolet light when using OCUFLOX®.
- Follow all your doctor's instructions carefully.
- Tell your doctor if your eye(s) infection seem(s) to be getting worse or is/are not improving.

# Call your doctor straight away if you:

- experience an eye injury, or have eye surgery
- become pregnant while using OCUFLOX®.

Remind any doctor, dentist, pharmacist, or optometrist you visit that you are using OCUFLOX®.

### Things you should not do

 Do not to touch the dropper tip against your eye, eyelid, or anything else, to avoid contaminating the eye drops and to avoid injury to the eye caused by the tip.  Do not stop using OCUFLOX® earlier than instructed, or use it for longer than instructed or change the dose without checking with your doctor, even if you think you are better.

## **Driving or using machines**

Wait for your vision to clear after using OCUFLOX® before you drive or use machines.

# Looking after your medicine

Follow the instructions on the carton and bottle label on how to take care of your medicine properly.

Store it in a cool place away from heat or sunlight; for example:

do not store it in the car or on window sills.

Keep it where young children cannot reach it.

## When to discard your medicine

Discard the bottle 4 weeks after first opening it.

### Getting rid of any unwanted medicine

If your doctor advises that you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

# 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

The most common side effects when using OCUFLOX® are burning or stinging eye. These side effects are usually temporary and mild. While less common, the most serious side effects of OCUFLOX® are severe allergic reactions. See the information below and, if you need to, ask your optical practitioner, doctor or pharmacist if you have any further questions about side effects.

#### Less serious side effects

Less serious side effects	What to do
<ul> <li>Effects on the eye:</li> <li>burning, stinging, watering eye</li> <li>blurred vision</li> <li>itchy eyes, eyelid(s)</li> <li>feeling something in the eye</li> <li>unable to tolerate sunlight or other bright light</li> </ul>	Speak to your doctor if you have any of these less serious side effects and they worry you.
<ul><li>eye redness</li><li>swelling eyelid</li></ul>	

Less serious side effects	What to do
• dry eye	
• eye pain	
Effects on the body as a whole:	
<ul><li>skin rash or hives</li><li>Nausea</li></ul>	

## Serious side effects

Serious side effects	What to do
<ul> <li>Effects on the eye:</li> <li>blurred vision</li> <li>inflamed eye(s)</li> <li>Effects on the body as a whole:</li> <li>Dizziness</li> </ul>	Call your doctor straight away, if you notice any of these serious side effects.
Effects on the body as a whole:  • severe allergic reaction, including swelling of the tongue, lips and throat, difficulty breathing.	Go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

# Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at <a href="https://www.tga.gov.au/reporting-problems">www.tga.gov.au/reporting-problems</a>. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

# 7. Product details

This medicine is only available with a doctor's prescription.

#### What OCUFLOX® contains

Active ingredient	ofloxacin
(main ingredient)	
Preservative	benzalkonium chloride
Other ingredients (inactive ingredients)	<ul><li>hydrochloric acid</li><li>purified water</li><li>sodium chloride</li></ul>

sodium hydroxide

Do not take this medicine if you are allergic to any of these ingredients.

#### What OCUFLOX® looks like

OCUFLOX® is a clear, pale to light yellow-green solution. It is supplied in a white plastic dropper bottle containing 5 mL of liquid, which is enclosed in a carton. (Aust R 47485).

#### Who distributes OCUFLOX®?

OCUFLOX® is distributed in Australia by:

AbbVie Pty Ltd

Mascot NSW 2020

**AUSTRALIA** 

Ph: 1800 252 224

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